PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Gregory S. Kelley	Confirmation No.:	8007
Serial No.:	10/820,659	Examiner:	Christopher Koharski
Filing Date:	April 8, 2004	Group Art Unit:	3763
Docket No.:	1001.1755101	Customer No.:	28075

For: MEDICAL DEVICES INCLUDING AERATED ADHESIVE BONDS AND METHODS OF FORMING THE SAME

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Commissioner for Patents
P.O. Box 1450
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

CERTIFICATE FOR ELECTRONIC TRANSMISSION:
The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 26th day of December 2007.

By Kathleen L. Boekley
Kathleen L. Boekley

Dear Sir:

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this Request.

This Request is being filed with a Notice of Appeal.

The review is requested for the reasons stated on the attached five sheets of arguments.

This Request is signed by an attorney or agent of record.

Respectfully submitted,

Gregory S. Kelley

By his Attorney,

Date: 12/26/07

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Attachment: Five Sheets of Pre-Appeal Brief Request Attachment

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PRE-APPEAL CONFERENCE BRIEF

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By _____
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Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a prima facie rejection.

Claims 1-4 and 7 remain rejected under 35 U.S.C. §102(e) as being anticipated by Deniega et al. Applicant submits that this rejection is in error because Deniega et al. do not teach every element of the claimed invention. Deniega et al. teach that a distal end 285 of a non-porous tube 282 may be inserted into the lumen of porous tubular section 280 and that "preferably, a suitable type of medical adhesive is applied between the overlapping surfaces of the tube 282 and the tubular section 280, to hold the tubes 280, 282 together." Paragraph 108. The Examiner asserts that "the adhesive layer is prepared and dried in an ambient environment and thus inherently has some void spaces and is capable of having distensible regions within the adhesive layer." Deniega et al. are silent regarding the production environment and thus do not teach that the adhesive layer is prepared and dried in an ambient environment. However, even if this were true, the results do not inherently follow. MPEP 2112 IV. states:

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) ... "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is **necessarily present** in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'"

> *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)...
>
> "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

(Emphasis added). Applicant submits that the claimed device, in particular the aerated adhesive layer, is not necessarily present in Deniega et al. It appears the Examiner is asserting that the claimed aerated adhesive layer could be used in the device of Deniega et al., which is not a proper basis for an anticipation rejection. The Examiner has not provided any basis in fact and/or technical reasoning to reasonably support the assertion that the generic "suitable type of medical adhesive" taught by Deniega et al. is necessarily aerated.

In the Response to Arguments section of the Final Office Action the Examiner asserts that Applicant's specification lacks any specific definition of an aerated adhesive. The Examiner's attention is directed to the specification at, for example, page 11, lines 2-17, for a specific definition and explanation of an aerated adhesive. Deniega et al. do not teach such an aerated adhesive. The Examiner also asserts that any mentioned biocompatible medical adhesive will have some air voids present within the layer during manufacture and assembly and therefore qualifies as an aerated adhesive using the broadest reasonable definition. The Examiner has not provided any basis in fact and/or technical reasoning to support this assertion. The Examiner appears to be taking Official Notice of this asserted fact. Applicant submits that the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. Pursuant to MPEP 2144.04(C), Applicant respectfully traverses the taking of Official Notice and request the Examiner provide documentary evidence supporting the rejection if the rejection is maintained. For at least this reason, Applicant submits that the rejection of independent claim 1 and the claims dependent thereon over Deniega et al. is in error.

Claims 5-6 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Deniega et al. in view of Ferrera et al. As discussed above, Deniega et al. do not teach, expressly or inherently, an aerated adhesive. Ferrara et al. likewise fail to teach this element. The teaching of Ferrara et al. that the adhesive may be "an epoxy, a UV curable adhesive, or a cyanoacrylate

adhesive" does not require that the adhesive be an aerated adhesive. Neither Deniega et al. nor Ferrara et al. teach or suggest, singly or together, each and every element of the claimed invention, thus this rejection is also in error.

Claims 8 and 13 also remain rejected under 35 U.S.C. §103(a) as being unpatentable over Deniega et al. in view of Ferrera et al. The Examiner acknowledges that neither Deniega et al. nor Ferrera et al. teach the claimed voids and densities, but asserts that it would have been obvious to construct the aerated-adhesive with the void space and density for optimal joining performance. First, as discussed above, neither reference teaches an adhesive that is aerated or that has voids. Second and in part due to the fact that neither reference teaches an adhesive that is aerated or has voids, neither reference teaches that the percent volume of the voids or the effective density of the adhesive layer relative to the adhesive material is a result effective variable and thus a variable for which there is an optimum non-zero value. There is thus no teaching or suggestion of an aerated adhesive nor is there a suggestion or motivation to create an aerated adhesive found in the cited references. Further, neither references teaches or suggests that having voids or a particular density would create an optimal joining performance. The only indication of such "optimizing" is found in Applicant's specification. Applicant submits that the Examiner has failed to set forth a *prima facie* case of obviousness. Thus this rejection is also in error.

Claims 9-12 remain rejected under 35 U.S.C § 103(a) as being unpatentable over Deniega et al. in view of Jauchen et al. (U.S. Patent No. 6,180,544). As an initial matter, the Jauchen et al. reference is not a proper reference. To rely on a reference under 35 U.S.C. § 103, the reference must be analogous prior art. "To rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, be reasonably pertinent to the particular problem with which the inventor was concerned. MPEP 2141.01(a) citing *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). The field of Jauchen et al., self-stick plaster bandages and the like, is not in the field of the present application, catheters. Moreover, the Jauchen et al. reference cannot be said to be reasonably pertinent to the particular problem that the inventor of the present application is concerned with, namely bonding medical device components together with an adhesive that

resists stresses caused by adhesive curing. Applicant therefore respectfully submits that the use of Jauchen et al. as a reference under 35 U.S.C. § 103 is in error.

Notwithstanding the impropriety of the rejection, the rejection of claims 9-12 over Deneiga et al. in view of Jauchen et al. nevertheless fails to establish a *prima facie* case of obviousness because there is no suggestion or motivation to modify the reference or combine reference teachings. The Examiner argues that it would have been obvious to use the adhesive of Jauchen et al. with the catheter of Deniega et al. because the adhesive allows for improved joining. However, Jauchen et al. teach their air and water permeable adhesive for providing good skin compatibility and a cushioned effect, which are desirable properties for bandages. Jauchen et al. is directed to providing an adhesive bond between a bandage and human skin, which is why the air and water permeability of the adhesive is desired. Nowhere in Jauchen et al. or Deniega et al. is it suggested that such an adhesive would be desirable in bonding portions of a catheter as taught by Deniega et al. Deniega et al. teach that their joining techniques are quite adequate and do not recognize the problem that the inventor of the present application recognizes of potential delamination of the adhesive joint. Because the foamed adhesive of Jauchen et al. incorporates a substantial volume of air or other gasses in the form of voids or pockets, its strength per unit volume is necessarily lower than that of a non-foamed adhesive of the same material. The improved adhesion reported by Jauchen et al. therefore must come from an improved interface between the foamed adhesive and the skin. Foaming an adhesive produces an adhesive material with an irregular surface that is easily conformable, and one can infer that such a surface increases the surface area of adhesive that is actually sticking to the skin and that the improved adhesion reported comes from this increased area of adhesive that is in contact with the irregular surface of the skin. One also notes that the adhesive layer of the bandage, when it is stuck to the skin, is in a solid (and not a liquid) state. Thus one can see that the factors which make the foamed adhesive an improved adhesive for the purposes of Jauchen et al. are inapplicable to the manufacture of catheters. In the manufacture of catheters, such as those of Deniega et al., the two components are fixed together with the adhesive in a liquid state and the adhesive is then cured with the components in place. There is no reasonable expectation of success in using the foamed adhesive of Jauchen et al. in the manufacture of a catheter as taught by Deniega et al. Applicant therefore respectfully submits that there is no motivation to

combine the references and, consequently, that there is no *prima facie* case of obviousness. The rejection is thus in error.

Claims 14-15 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Deniega et al. Claims 14-15 depend from claim 1, which recites "an aerated adhesive layer," which, as described above, is not disclosed or suggested by Deniega et al. The Examiner argues that it would have been obvious to one of ordinary skill in the art to adjust the adhesive layer to desired thickness for optimal joining and reliability. However, "a particular parameter must be first recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." MPEP 2144.05 citing *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Applicant can find no indication in Deniega et al. that the gap between the two tubes is recognized as a result-effective variable; optimization of the gap therefore cannot be regarded as routine. To the contrary, Jauchen et al. teach that "preferably the tubular section 280 has an outer diameter of about 0.042 inches and has an inner diameter sized so that the distal end 285 of the tube 282 fits snugly within the proximal end 287 of the lumen 281, as shown in Figure 26A." Paragraph 110. In the other words, not only is the gap between these two tubes not a result-effective variable, it isn't even a variable in the thinking of Jauchen et al. and it preferably doesn't even exist.

Claims 16-18 remain rejected as being unpatentable over Deniega et al. in view of Klima et al. As discussed above, Deniega et al. do not disclose an aerated adhesive as recited in claim 1. Klima et al. do not remedy this deficiency. The rejection is thus also in error.

Respectfully submitted,

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